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1. Purpose/Policy

To describe the procedure for initiating, receiving, resolving and maintaining records of complaints relating to the quality of the Medical Device Single Audit Program (MDSAP) work products, processes and services; and other customer feedback. Complaints can provide valuable feedback on the effectiveness of the organization and can be used to improve the Medical Device Single Audit Program with the customer in mind.

2. Scope

This procedure applies to the MDSAP Team's work products, processes, services; and the MDSAP Quality Management System.

3. Definitions/Acronyms

Complaint: any written, electronic, or oral communication that alleges deficiencies or expression of dissatisfaction related to MDSAP processes, products, or services. This includes alleged deficiencies or expression of dissatisfaction related to the MDSAP auditing organizations and manufacturers. Complaints are also objections, errors, or nonconformities involving work quality, or failures to provide service or other requests of the customer including timeliness.

Correction: Action to eliminate a detected nonconformity. (ISO 9000:2005)

Corrective Action (CA): Action to eliminate the cause of a detected nonconformity or other undesirable situation. (ISO 9000:2005).

Escalation: The process by which MDSAP can escalate a complaint or other feedback to the Regulatory Authority Council (RAC) for final determination when

necessary.

Feedback: Communication from customers (internal and external) about how delivered products or services compare with customer expectation. (ASQ - Quality Glossary)

4. Authorities/Responsibilities

MDSAP Regulatory Authority Council (RAC) is responsible for:

- Review and analyze trends and recurrences of Nonconformances, complaints and recommend appropriate remedial action.
- Has final authority of the disposition of all complaints and other issues arising from customer feedback.

MDSAP Lead Project Manager is responsible for:

- Ensuring implementation of the complaints and other feedback procedure and for facilitating process changes when necessary.
- Collaborating with project managers and other stakeholders on the evaluation of the complaint or feedback and the determination of what (if any) process or product changes are needed.
- All MDSAP team members may be responsible for recording complaints and/or other feedback received on the MDSAP QMS F0011.1 Complaint and/or Customer Feedback (CF) Form.

The receiver of the complaint or feedback (i.e. project managers) is responsible for:

- Initiating corrective action (when appropriate) according to the MDSAP QMS P009 Corrective Action (CA) Procedure.
- Forwarding the CF form to the appropriate individual(s) for assessment and, if indicated, further processing.
- Working with management and/or process owner to assess and investigate complaints and feedback.
- Recommending the type of corrective action (when appropriate) to management, and
- Monitoring and performing follow-up action to ensure resolution is satisfactory and complete.

Regulatory Authority Corrective Action (RA/CA) Contact is responsible for:

- Review the nonconformity –complaint and customer feedback to determine if the issue should be raised to a corrective action or closed with a correction and referred back to the CA/PA Administrator. If a corrective action is required, the RA/CA Contact will assign the nonconformity to a CA Assignee within his/her organization. Each Regulatory Authority must designate an RA/CA contact.

5. Procedures

Complaint and/or Customer Feedback Form (CF) may be initiated and submitted in written format, electronically, by telephone, or in person.

Complaint and/or customer feedback forms (CFs) are identified by three (3) categories:

- Source A – complaints and/or feedback received internally within the MDSAP Team.
- Source B – complaints and/or feedback received from MDSAP Regulatory Authority components outside the MDSAP Team.
- Source C – complaints and/or feedback received from outside participating MDSAP Regulatory Authorities.

Receiving Complaints and/or Customer Feedback

Document complaints and/or customer feedback on the Complaint and/or Customer Feedback (CF) Form.

The Complaint and/or Feedback Form must include, at a minimum:

- The name and affiliation of the complainant
- The name of the individual logging the complaint
- The date the complaint was received, and
- The nature of the complaint.

Processing Complaints

- If the person receiving the complaint identifies that a known correction may be implemented, they should undertake the correction, complete the Complaint Form (CF) and forward to the RAC Secretariat. The RAC Secretariat will populate the Complaint database with information from the CF and forward the CF to the CA/PA Administrator for further evaluation.
- If a correction is not known, or the cause and corrective action cannot be determined by the person receiving the complaint, submission of the complaint is still made by entering as much as possible in information on the Complaint Form (CF) and forward to the RAC Secretariat. Any complaint that cannot be resolved is referred to the next higher level of management.
- The individual that is assigned the complaint is responsible for updating the Complaint Database, as necessary. (e.g. RAC Secretariat will only populate the database when a complaint/feedback is received) A corrective action report is generated and the MDSAP's corrective action process initiated. This process involves the determination and investigation of adverse impact on operations and quality.
- The RAC Secretariat will monitor the progress of the complaint or customer feedback.

- Unsubstantiated Complaints and/or Customer Feedback that does not represent a substantiated complaint are to be forwarded to the Lead Project Manager for disposition.

Closing and Monitoring Complaints

- When the corrective action has been completed, the complaint is closed. The complaint form and corrective action form is submitted to the RAC Secretariat electronically.
- MDSAP Lead Project Manager will then review the completed forms to determine if the action taken is effective, efficient and satisfactorily completed or if further follow-up action is needed. If satisfactorily completed the Lead Project Manager signs off on the forms.
- If follow-up action is needed, a follow-up date shall be determined and documented.
- MDSAP Project Manager will need to subsequently ensure follow-up is completed, satisfactory and documented in the system.
- When the corrective action has been successfully completed, the complaint is considered closed out.
- RAC Secretariat will then notify the final corrective action and disposition of the complaint to all entities involved in this process, and
- Internal audits, and eventually MDSAP management reviews, system tracking and trending will determine if changes resulting from complaints were proper, effective, timely and successful.

Determination and Investigation of Adverse Impact/Nonconformity

- The individual assigned to the complaint will assess (risk analysis) the complaint to determine any adverse impact / hazard associated on the quality of MDSAP products, processes, and / or services.
- If it is determined that the complaint has an adverse impact, and correction or corrective action has not been initiated by the complaint recipient, the individual assigned to the complaint may recommend corrective action, by communicating via e-mail to the CA/PA Administrator using the MDSAP QMS F0006.1 Nonconformity Report (NCR) Form.
- If a corrective action is required, the RA/CA Contact will assign the nonconformity to a CA Assignee within his/her organization. When necessary, the RA/CA Contact will consult with the MDSAP Team Lead Manager to make this determination. Once a decision is made, the RA/CA Contact will email the CA/PA Administrator indicating whether or not the issue was accepted as a CA into the CA/PA system, the email will contain the target completion date along with the CA Assignee who will be responsible for the CA and proceed with the process as described in the MDSAP QMS P0009 Corrective Action (CA) Procedure.

Feedback

Customer feedback other than complaints may be considered “continuous improvement” suggestions.

- Customer feedback may include but is not limited to:
  - Suggestions for process changes that will improve efficiency or quality;
  - Ideas for new services;
  - Comments on recognition of high quality work products or services.
- Document customer feedback by completing the CF form and forward to the RAC Secretariat for entry into the database.
- The RAC Secretariat maintains records of customer feedback. Customer feedback is included and evaluated in the MDSAP management review process.
- Activities associated with Customer Feedback should be documented on the CF form, and
- The RAC Secretariat will monitor the progress of the customer feedback.

6. Forms

MDSAP QMS F0006.1 - Non-Conformity Report (NCR) Form
MDSAP QMS F0009.1 - Corrective Action Report/Problem (CARP) Form
MDSAP QMS F0011.1 - Complaint and/or Customer Feedback (CF) Form and Instruction
MDSAP QMS F0011.2 - Complaint and/or Customer Feedback Flowchart

7. Reference Documents

MDSAP QMS P0009 - Corrective Action (CA) Procedure

8. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2013-07-15	Initial Release	Liliane Brown

Version
Approval

Approved: Chair, MDSAP RAC - Signature on file Date: 2013/07/16